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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/716,531 09/19/96 MAHE Y 016800-111

<input type="checkbox"/>	HM21/1207	<input type="checkbox"/>	EXAMINER
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<input type="checkbox"/>	ART UNIT	<input type="checkbox"/>	PAPER NUMBER
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<input type="checkbox"/>	1642
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DATE MAILED: 12/07/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/761,531</b>	Applicant(s) <b>Mahe</b>
	Examiner <b>Sheela J. Huff</b>	Group Art Unit <b>1642</b>

Responsive to communication(s) filed on 4/15/98 and 7/27/98

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-11 and 16-19 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-11 and 16-19 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

1. It is noted that applicant's requested an interview with the Examiner. The tried several times to contact the attorney of record, Robin Teskin, to set up an interview (attempts were made in October of 1998). While the attorney did respond (by voice mail) that an interview was still desired the attorney never returned the Examiner's last phone call to actually set up an interview.

#### ***Continued Prosecution Application***

2. The request filed on 4/15/98 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/716531 is acceptable and a CPA has been established. An action on the CPA follows.

3. The amendment filed 3/13/98 has been entered.

4. Claims 1-11 and 16-19 are pending.

5. The rejections under 35 U.S.C. 112, first paragraph, and 35 U.S.C. 112, second paragraph are withdrawn in view of applicant's amendment.

6. Applicant's arguments filed 1/15/98 and 3/13/98 have been responded to in papers no. 9 and 11. Only the declaration will be responded to in this action.

#### ***Response to Argument***

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***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferreira et al US 5389615 or Oluyomi et al Eur. J. Pharm. vol. 258 p. 131 (1994). The reasons for this rejection are of record in paper no. 4.

Applicant filed a declaration to overcome the Oluyomi et al reference.

Applicant argues that the reference is directed to the inhibition of pain.

Applicant is direct to papers no. 6, 9 and 11 which detail the Examiner's reasoning that the reference is dealing with the treatment of inflammation (ie inflammatory pain).

Applicant argues that Oluyomi et al and Hiltz et al (1991) must be read together.

Applicant argues that the Hiltz et al reference only shows that the L-Pro form is active and that the reference clearly states this. While the reference does state this, applicant is requested to carefully analyze both references together. First of all, applicant is NOT claiming the NH<sub>2</sub> form of the peptide. Secondly, the reference is a 1991 reference and the Oluyomi et al reference, which is a 1994 reference, clearly shows that lys-D-pro-valNH<sub>2</sub> is effective in the **late phase** (see page 137 (col. 1, lines 6-8)). It is not clear which phase of inflammation Hiltz et al is referring to when they say that it is inactive.

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Since there are several phases of inflammation and since it is not clear if both references were testing activity in the same phase and since Oluyomi et al is a 1994 reference which clearly shows activity in the late phase, absent objective evidence to the contrary, the Oluyomi et al reference supersedes the Hiltz et al reference.

Applicant is also directed to the last sentence on page 137 which states that "**We conclude that useful analgesics may be developed from peptides containing the sequence Lys-D-Pro-X"**(emphasis added). Thus, the 1994 reference does show and believe that peptides containing D-pro are anti-inflammatory.

In item 10 of the declaration, applicant cites several references. These reference are not record and not currently available to the Examiner for consideration.

For the above reasons, the Examiner disagrees with applicant's opinion that the D-Pro containing peptides are ineffective in treating inflammation.

Applicant did not present any arguments to the Ferreira et al US 5389615 reference.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 4, 7-10 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over by Ferreira et al US 5389615 as applied to claims 1-3 above. The reasons for this rejection are of record in paper no. 4.

Applicant did not present any new arguments to this rejection.

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12. Claims 5-6 and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over by Ferreira et al US 5389615 as applied to claims 1-3 above further in view of Lipton US 5157023 and Oluyomi et al Eur. J. Pharm. vol. 258 p. 131 (1994). The reasons for this rejection are of record in paper no. 4.

Applicant did not present any new arguments to the Ferreira et al or Lipton references. Applicant's arguments to Oluyomi et al have been addressed above.

13. Claims 1-11 and 16-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over by Ferreira et al US 5389615 in view of Norlund et al US 4874744, Lipton US 5157023 and Remington's Pharmaceutical Sciences, 16th ed. (1980), Ch. 87 and 92 and Oluyomi et al Eur. J. Pharm. vol. 258 p. 131 (1994). The reasons for this rejection are of record in paper no. 4.

Applicant did not present any new arguments to the Ferreira et al, Remington's, Norlund or Lipton references. Applicant's arguments to Oluyomi et al have been addressed above.

14. Claims 1-3, 5-11 and 16-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Oluyomi et al Eur. J. Pharm. vol. 258 p. 131 (1994) in view of Norlund et al US 4874744, Lipton US 5157023 and Remington's Pharmaceutical

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Sciences, 16th ed. (1980), Ch. 87 and 92. The reasons for this rejection are of record in paper no. 4.

Applicant did not present any new arguments to the Remington's, Norlund or Lipton references. Applicant's arguments to Oluyomi et al have been addressed above.

***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant is directed to the claims of Ferreira et al US 5580855.

16. This is a CPA of applicant's earlier Application No. 08/7165531. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The Examiner can normally be reached on Monday, Wednesday and Friday from 6:30am to 4:00pm and Tuesday 1:00pm to 5:00pm.

If attempts to teach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached on (703)308-4310.

The FAX phone number for the group is (703)308-4242.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].

All Internet e-mail communications will be made of record in the application file.

**PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Sheela J. Huff  
December 4, 1998



Sheela J. Huff  
Primary Examiner